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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/022,996	
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	First Named Inventor	Joseph R. Callof	
	Art Unit	3731	
	Examiner Name	Michael H. Thaler	
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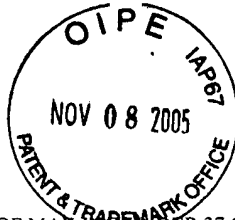
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

JOSEPH R. CALLOL ET AL.

Serial No. 10/022996

Filed: December 17, 2001

For: STENT FOR TREATING  
BIFURCATIONS AND METHOD OF  
USE

Examiner: Michael H. Thaler

Group Art Unit 3731

Docket No. ACS 57812

November 3, 2005

Los Angeles, California 90045

APPEAL BRIEF

Mail Stop Appeal Brief - PATENTS  
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This Appeal Brief is responsive to the office communication by the Examiner, dated October 6, 2005. This Appeal Brief is being filed within the term provided as permitted under 37 C.F.R. § 1.192(a) and is in compliance with 37. CFR 41.37.

## **INTRODUCTION**

The present invention relates to stents and methods for delivery and deployment of stents used at a blood vessel bifurcation. More particularly the invention relates to a method for delivering one or more stents for repairing bifurcations and blood vessels that are diseased. The invention further relates to a method for treatment of a main vessel and the opening of a side branch vessel at a bifurcation including delivery and implementation of the stents. Generally, stents are tiny mesh tubes that are implanted in blood vessels, such as coronary arteries, to hold open the artery so that normal blood flow is maintained. The present application, U.S. Serial No. 10/022996 was filed on December 17, 2001.

A Notice of Appeal from the Final Office Action of February 15, 2005 and from the Advisory Action of May 4, 2005 was filed on May 13, 2005. The two month deadline from the Notice of appeal date is July 13, 2005, and this Appeal Brief is being filed within the term provided as permitted under 37 C.F.R. § 1.192(a). This appeal has one core issue which is whether the claimed invention is obvious under 35 U.S.C. §103(a) in view of the references cited by the Examiner. Appellant has presented strong arguments for non-obviousness in view of the references cited by the Examiner.

## **REQUEST FOR ORAL ARGUMENT**

An oral argument is requested.

## **I. REAL PARTY IN INTEREST**

The real party in interest is ADVANCED CARDIOVASCULAR SYSTEMS, INC. This application was originally assigned by the inventors, JOSEPH R. CALLOL and W. STAN WILSON to ADVANCED CARDIOVASCULAR SYSTEMS, INC., by assignments executed April 4, 2002 and January 23, 2002 which were recorded by the Patent Office on April 11, 2002 beginning at reel 012783, frame 0285.

## **II. RELATED APPEALS AND INTERFERENCES**

None.

## **III. STATUS OF CLAIMS**

This patent application has 7 pending claims. Of the originally filed 14 claims, Claims 1-7 were canceled because of a restriction requirement. Pending Claims 8-14 were finally rejected in an Office Action dated February 15, 2005, and were also rejected in the Advisory Action of May 4, 2005.

Claims 8-14 are pending in the application and claims 8-14 are appealed. A copy of the claims appealed is attached hereto as Exhibit 1.

Claims 8-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lam (5,607,444) in view of Kim (6,270,524). (Copies of U.S. Patent Nos. 5,607,444 and 6,270,524 are attached hereto as Exhibit 2).

#### **IV. STATUS OF AMENDMENTS**

##### **First Office Action June 28, 2004** (a copy of which is attached as Exhibit 3)

In a first Office action dated June 28, 2004 the Examiner subjected claims 1-14 to a restriction requirement. The Examiner grouped claims 1-7 to a first invention and claims 8-14 to a second invention.

##### **Amendment Dated July 9, 2004** (a copy of which is attached as Exhibit 4)

In a first amendment dated July 9, 2004, the Applicants:

- elected to prosecute claims from the second group, claims 8-14
- canceled claims 1-7

##### **Second Office Action September 24, 2004** (a copy of which is attached as Exhibit 5)

In a second Office action dated September 24, 2004, the Examiner:

- rejected claims 8-14 as being unpatentable under 35 U.S.C. §103(a) over Lam (U.S. Pat. No. 5,607,444) in view of Kim (U.S. Pat. No. 6,270,524).

##### **Amendment Dated December 22, 2004** (a copy of which is attached as Exhibit 6)

In an Amendment dated December 22, 2004, the Applicants:

- amended independent claim 8 and dependent claim 9
- presented arguments to overcome the rejections under 35 U.S.C. §103(a).

##### **Final Office Action February 15, 2005** (a copy of which is attached as Exhibit 7)

In a Final Office Action dated February 15, 2005, the Examiner:

- rejected claims 8-14 as being unpatentable under 35 U.S.C. §103(a) over Lam (U.S. Pat. No. 5,607,444) in view of Kim (U.S. Pat. No. 6,270,524).

##### **Amendment Dated April 13, 2005** (a copy of which is attached as Exhibit 8)

In an Amendment after final dated April 13, 2005 the Applicants:

- presented arguments to overcome the rejections under 35 U.S.C. §103(a).

Advisory Action May 4, 2005 (a copy of which is attached as Exhibit 9)

In an Advisory Action dated May 4, 2005, the Examiner:

- stated that the reply dated April 13, 2005 failed to put the application in condition for allowance

Notice of Appeal Dated May 13, 2005 (a copy of which is attached as Exhibit 10)

Notice of Appeal Dated May 13, 2005 was filed by Applicant.

## **V. SUMMARY OF THE INVENTION**

The present invention includes a method of delivering a bifurcated stent (20).

More specifically, the present invention is a method for treating the proximal portion of a main vessel (6) and the opening of a side branch vessel (5) at a bifurcation.

In one embodiment, a method of delivering and implanting a stent (20) mounted on a catheter assembly (101) are disclosed in the present invention. The bifurcated catheter assembly (101) of the present invention provides two separate balloons (117) (129) in parallel which are advanced into separate passageways of an arterial bifurcation and the balloons (117) (129) are inflated either simultaneously or independently (or a combination thereof) to expand and implant the stent (20). More specifically, and in keeping with the invention, the catheter assembly (101) is advanced through a guiding catheter (not shown) until the distal end of the catheter assembly (101) reaches the ostium to the coronary arteries. A rapid exchange (Rx) guide wire is advanced out of the Rx

shaft and into the coronary arteries to a point distal of the bifurcation or target site. In a typical procedure, the Rx guide wire will already be positioned in the main vessel after a pre-dilatation procedure. The catheter assembly (101) is advanced over the Rx guide wire so that the catheter distal end (102) is just proximal to the opening to the side branch vessel (5). Up to this point in time, an over-the wire (OTW) guide wire (or mandrel or joining wire) remains within the catheter assembly (101) and within the coupler so that the long balloon (117) and the short balloon (129) of the catheter assembly (101) remain side by side to provide a low profile. As the catheter assembly (101) is advanced to the bifurcated area, the coupler moves axially relative to the distal end of the OTW guide wire (or mandrel or joining wire) a small distance (approximately 0.5 mm up to about 5.0 mm), but does not pull completely out of the coupler, making it easier for the distal end of the catheter to negotiate tortuous turns in the coronary arteries. Thus, the slight axial movement of the coupler relative to the OTW guide wire (or mandrel or joining wire) distal end allows the catheter tips to act or move independently, thereby increasing flexibility over the tips joined rigidly and it aids in the smooth tracking of the catheter assembly (101) over the Rx guide wire. The proximal end of the OTW guide wire is releasably attached to a proximal hub. The OTW guide wire (or mandrel or joining wire) is removed or withdrawn proximally from the coupler, thereby uncoupling the long balloon (117) and the short balloon (129). Thereafter, the OTW guide wire is advanced distally into the side branch vessel so that the catheter assembly can next be advanced distally over the Rx guide wire (116) in the main vessel (6) and the OTW guide wire in the side branch vessel (5). The separation between the Rx guide wire (116) and the OTW

guide wire allows the long balloon (117) and the short balloon (129) to separate slightly as the catheter assembly (101) is further advanced over the Rx guide wire (116) and the OTW guide wire. The catheter assembly (101) advances distally until it reaches a point where the distal end of the stent (20) is approximately adjacent to the opening to the side branch vessel (5), so that the catheter assembly (101) can no longer be advanced distally since the stent (20) is now pushing up against the opening to the side branch vessel (5). One or more radiopaque markers are placed on the distal portion of the catheter assembly (101) to aid in positioning the stent (20) with respect to the bifurcation or target site. Once the long (117) and short balloons (129) with the stent (20) mounted thereon are positioned in the main vessel (6) just proximal to the side branch vessel (5), the long balloon (117) and the short balloon (129) are next inflated simultaneously or independently (or a combination thereof), to expand the stent (20) in the main vessel (6) and the opening to the side branch vessel (5). The distal portion of the stent (20) is expanded into contact with the opening to the side branch vessel (5) and the distal opening should substantially coincide with the opening to the side branch vessel (5) providing a clear blood flow path through the proximal opening of the stent (20) and into the side branch vessel (5). By inflating the long balloon (117) and the short balloon (129) substantially simultaneously, plaque shifting is avoided and better vessel wall coverage results. After implanting the stent (20), the distal opening will have a substantially elliptical shape due to the shape of the vessel opening. In this embodiment, the proximal section of the stent (20) apposes the main vessel (6) wall at a location proximal to the



opening to the side branch vessel (5) so that the stent (20) does not cover the main vessel (6) distal to the bifurcation which does not require repair or treatment.

The one independent claim, claim 8, is supported by at least the following references to the specification, reference characters, and figures:

A method for treating the proximal portion of a main vessel (6) and the opening of a side branch vessel (5) at a bifurcation (page 26, line 14 – page 27, line 13) (FIGS. 35-39), comprising:

providing a stent (20) having a plurality of first rings (26) (29) and a plurality of second rings (28) (page 28, lines 22-27) (FIGS. 6-20);

mounting the stent (20) on a catheter (101) having a long balloon (117) and a short balloon (129) wherein the long balloon (117) and short balloon (129) are positioned side by side (page 48, line 9 – page 49, line 20) (FIGS. 23-34);

advancing the catheter (101) and stent (20) through the vascular system to a position proximal of the bifurcation (page 50, lines 14 – 25) (FIG. 35);

positioning the stent (20) at the bifurcation so that the second rings (28) are aligned with the opening to the side branch vessel (5) (page 52, lines 1-15) (FIG. 39);

inflating the long balloon (117) and the short balloon (129) to radially expand the stent (20) so that the first rings (26) (29) appose and contact the main vessel (6) proximal to the bifurcation and the second rings (28) appose and contact the opening of the side branch vessel (5) (page 52, lines 15-24) (FIGS. 40-41); and

deflating the long balloon (117) and the short balloon (129) and withdrawing the catheter (101) from the vascular system (page 53, lines 24-26).

## **VI. ISSUES ON APPEAL**

In the Final Office Action dated February 15, 2005, the Examiner rejected claims 8-14 under 35 U.S.C. §103(a) as being unpatentable over Lam (5,607,444) in view of Kim (6,270,524). The Examiner argued that Lam discloses the steps of providing a stent having a first section and a second section, mounting the stent on a catheter having a long balloon and a short balloon, wherein the long balloon and short balloon are positioned side by side. The Examiner further asserted that in the configuration shown in Figure 7, the balloons are positioned side by side because the short balloon curves downwardly "near the side of the long balloon."

In view of the Examiner's rejections, Appellant respectfully submits that the issue is as follows:

Issue 1. Are claims 8-14 patentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,607,444 to Lam in view of U.S. Patent No. 6,270,524 to Kim.

## **VII. GROUPING OF CLAIMS**

Claims 8-14 stand or fall together.

## **VIII. ARGUMENT**

### **ISSUE 1**

In the Final Office Action dated February 15, 2005, the Examiner rejected claims 8-14 under 35 U.S.C. §103(a) as being unpatentable over Lam (5,607,444) in view of Kim (6,270,524). The Examiner dismissed Appellant's argument that the Lam patent

does not teach or disclose "mounting the stent on a catheter having a long balloon and a short balloon wherein the long balloon and short balloon are positioned side by side."

The Examiner stated that the balloons are positioned side by side because the short balloon curves downwardly "near the side of the long balloon" in Figure 7 of Lam.

Appellant maintains that Lam does not teach mounting the stent on a catheter having a long balloon and a short balloon, wherein the long balloon and the short balloon are positioned side by side. Appellant further asserts that Lam teaches away from the balloons being positioned side by side during the insertion of the stent.

**A. THE PRESENT INVENTION CLAIMS ARE PATENTABLE OVER  
LAM IN VIEW OF KIM**

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In the Final Office Action dated February 15, 2005, the Examiner rejected claims 8-14 under 35 U.S.C. §103(a) as being unpatentable over Lam (5,607,444) in view of Kim (6,270,524). The rejection based on Lam in view of Kim was first brought in the second Office Action dated September 24, 2004. The Examiner has maintained this rejection notwithstanding Appellant's amendments and overwhelmingly strong arguments provided in each response.

Independent claim 8 recites in pertinent part "mounting the stent on a catheter having a long balloon and a short balloon wherein the long balloon and the short balloon are positioned side by side." Neither the Lam nor Kim prior art references teach or suggest mounting a stent on a catheter having a long balloon and a short balloon wherein

the long balloon and the short balloon are positioned side by side. For this reason alone, claim 8 is patentably distinguishable over Lam and Kim.

In the Advisory Action mailed May 4, 2005, at page 2, the Examiner argued that claim 8 does not specify if the balloons are positioned side by side "1) before the mounting step (in line 5), 2) after the mounting step, 3) during the mounting step or 4) all three of the above time periods." The Examiner further argued that claim 8 does require that the long balloon and the short balloon be positioned side by side but is silent as to when this occurs relative to the other steps in the claim. Appellants' position is that claim 8 cannot be any more clear. Claim 8 requires the stent to be mounted on the catheter which has a long balloon and a short balloon where the long balloon and the short balloon are positioned side by side. In other words, the stent is mounted on the long balloon and the short balloon while they are side by side. Nothing can be more clear.

Focusing on the Examiner's Advisory Action statement regarding the timing of the mounting of the stent, clearly the balloons cannot be positioned side by side after the stent is mounted on the balloons. Thus, items 3 and 4 of the Examiner's argument (set forth above) are obviated. Further, it is irrelevant whether the balloons are side by side "before the mounting step" or "during the mounting step" since the prior art to Lam does not show either claim element. Accordingly, the Examiner's arguments set forth in the Advisory Action must fail.

Notwithstanding the semantics raised by the Examiner with respect to the time relationship of when the stent is mounted on the long balloon and the short balloon, the fact remains that the Lam prior art patent does not show a stent being "mounted" on a

catheter where the balloons are side by side. There is no teaching anywhere in the Lam patent regarding balloons being positioned side by side. Absent a teaching in Lam of mounting the stent on balloons positioned side by side, the rejection of the claims under 35 U.S.C. § 103 should be overturned.

Further, neither Lam nor Kim disclose a long balloon and a short balloon positioned side by side for deploying a stent at a bifurcation. There is no suggestion or teaching in either Lam or Kim that two balloons, one being long and the other being short, positioned side by side, would be capable of delivering any of the stents disclosed in the prior art references.

The Lam patent discloses multiple balloons axially aligned, not side by side. Once the distal portion of one of the balloons is positioned in a bifurcated vessel and inflated, only then does a portion of the most distal balloon become oriented at an angle to the proximal balloon. Lam does not teach how the most distal balloon may be deployed so as to reverse direction one hundred and eighty degrees to come into position along the side of the other proximally located balloon, even after inflation. As shown in Figure 7 of Lam, the most distal balloon in fact diverges away from the proximal balloon as the most distal balloon is inflated. In fact, the divergent orientation of the most distal balloon in relationship to the proximal balloon illustrated in Figure 7 of Lam teaches away from the long balloon and the short balloon (taught by the present invention) being positioned side by side at any time.

Further, again referring to claim 8, it recites in pertinent part "advancing the catheter and stent through the vascular system to a position proximal of the bifurcation."

As the catheter and stent are being advanced through the vascular system to the position proximal of the bifurcation, the stent remains mounted on the long balloon and the short balloon which are positioned side by side. This method step is not shown in Lam nor is it possible based on the construction of the Lam catheter where the balloons are oriented axially along the catheter shaft. Thus, claim 8 is patentably distinguishable over the Lam prior art reference and the rejection under 35 U.S.C. § 103(a) should be reversed. Likewise, dependent claims 9-14 are distinguishable over the Lam prior art reference at least for the same reasons as independent claim 8 and the rejection of dependent claims 9-14 should be withdrawn.

The Kim patent does not teach any particular type of balloon catheter for use in delivery of the stent disclosed therein. Further, Kim fails to disclose any type of stent structure that arguably could be mounted on two balloons mounted side by side as set forth in claim 8 of the present application. Thus, the Kim patent adds nothing to the shortcomings of the Lam patent in maintaining the rejection of claims 8-14.

Accordingly, it is urged that claims 8-14, as amended, are patentably distinguishable over the cited art and that the rejection under 35 U.S.C. § 103(a) should be reversed.

**IX. CONCLUSION**

For the foregoing reasons, it is submitted that the present invention as claimed is not rendered obvious by Lam (5,607,444) in view of Kim (6,270,524), and that the Examiner's rejections of Claims 8-14 were therefore erroneous. Appellant respectfully requests reversal of the rejection of Claims 8-14.

Respectfully submitted,

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**LIST OF EXHIBITS**

<u>EXHIBIT</u>	<u>DESCRIPTION</u>
1	Appealed Claims
2	U.S. Patent No. 5,607,444 to Lam and U.S. Patent No. 6,270,524 to Kim
3	First Office action dated June 28, 2004
4	Amendment filed July 9, 2004
5	Second Office action dated September 24, 2004
6	Amendment filed December 22, 2004
7	Final Office action dated February 15, 2005
8	Amendment filed April 13, 2005
9	Advisory Action dated May 4, 2005
10	Notice of Appeal filed May 13, 2005



**EXHIBIT 1.**

**CLAIMS ON APPEAL:**

8. A method for treating the proximal portion of a main vessel and the opening of a side branch vessel at a bifurcation, comprising:

providing a stent having a plurality of first rings and a plurality of second rings;

mounting the stent on a catheter having a long balloon and a short balloon wherein the long balloon and short balloon are positioned side by side;

advancing the catheter and stent through the vascular system to a position proximal of the bifurcation;

positioning the stent at the bifurcation so that the second rings are aligned with the opening to the side branch vessel;

inflating the long balloon and the short balloon to radially expand the stent so that the first rings appose and contact the main vessel proximal to the bifurcation and the second rings appose and contact the opening of the side branch vessel; and

deflating the long balloon and the short balloon and withdrawing the catheter from the vascular system.

9. The method of claim 8, wherein the second rings form a substantially elliptical cross-section when expanded to appose and contact the opening to the side branch vessel.

10. The method of claim 8, wherein the stent is expanded in the main vessel so that substantially no portion of the stent is distal of the side branch vessel.

11. The method of claim 8, wherein the catheter includes a rapid exchange (RX) guide wire passageway for receiving an RX guide wire and an over-the-wire (OTW) guide wire passageway for receiving an OTW guide wire so that as the stent is positioned at the bifurcation, the catheter is slidably advancing over the RX guide wire and the OTW guide wire.

12. The method of claim 11, wherein as the catheter is advanced through the vascular system, the catheter slides over the RX guide wire positioned in the main vessel while a distal end of the OTW is positioned within a blind lumen.

13. The method of claim 12, wherein after the catheter is positioned proximal to the bifurcation, the OTW guide wire is withdrawn from the blind lumen and advanced into the side branch vessel.

14. The method of claim 13, wherein after the OTW guide wire is advanced into the side branch vessel, the catheter is advanced distally over the RX guide wire and the OTW guide wire to position the stent at the bifurcation.